

### **DETAILED ACTION**

1. A response and amendment were received and entered on June 22, 2010. All evidence and arguments have been fully considered. Claims 1-28 are pending. Claims 10-28 have been withdrawn due to a previous requirement for restriction. Claims 1-9 are examined on the merits in this Office action.

### ***Response to Amendment***

2. The amendment to the claims filed on June 22, 2010 does not comply with the requirements of 37 CFR 1.121(c) because the deleted text in the amendments to the claims is not marked properly. Specifically, the text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. In applicant's response, these deleted items have been shown using a double strike-through, which renders the deleted text less legible than single strike-through. Applicant is advised to use single strike-through in subsequent amendments. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. **The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.** Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

Since the reply filed on June 22, 1010 appears to be *bona fide*, and because the intention of the amendments to the claims is easily understood, the amendment has been entered and the informality is noted in this Office action.

***Claim Rejections - 35 USC § 112***

3. Rejections under 35 USC 112 have been withdrawn due to amendment.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (Biomaterials, October 2003, 24:3969-3980) in view of Young (WO 03/018040 A1; document cited in previous action). The claims recite a composition useful for the prevention, inhibition or treatment Parkinson's disease in a mammal comprising: a) live pigmented cells derived from the substantia nigra area of the brain of a mammal or the retinal pigmented epithelium layer of a mammal; and b) a biodegradable polymer gel capable of photo-induced cross linking. The claims further recite that said biodegradable polymer gel further comprises a water soluble macromer

having poly(ethylene glycol)di-ethylphosphatidyl(ethylene glycol)methacrylate, or attachment proteins and growth factors to enhance the survival of pigmented cells after implantation. The claims further recite that the live pigmented cells are mixed with the polymer gel solution, wherein the polymer is present in the solution in an amount within a range of 10 to 20% weight polymer/volume of solution, and that the concentration of live pigmented cells is at least 200,000 cells/ml to about 800,000 cells/ml. The claims further recite that said growth factors are bFGF and EGF.

7. Wang teaches compositions comprising live cells and a biodegradable polymer gel capable of photo-induced crosslinking (abstract). The reference teaches that the polymer gel comprises a water soluble macromere having poly(ethylene glycol)di-ethylphosphatidyl(ethylene glycol)methacrylate (PhosPEG-dMA; abstract). The reference teaches that the polymer may be suitable for use with a number of cell types (p. 3979, col. 1, par. 2). The reference teaches that the polymer is present in the solution at 15 or 20% (p. 3971, section 2.6). The reference does not specifically teach that the compositions may comprise retinal pigmented epithelial cells.

8. Young teaches compositions comprising retinal pigmented epithelial cells, a biodegradable polymer and growth factors, such as EGF and bFGF (abstract, p. 21, lines 1-19, p. 26, lines 5-15). The reference teaches that the polymer may be replaced with other types of polymer, such as a hydrogel (p. 21, line 35-p. 22, line 3). One of ordinary skill in the art would have been motivated to combine the compositions of Wang and Young because Wang teaches that the hydrogel taught therein is desirable because it is biodegradable and may enhance tissue development (p. 3970, par. 2) and

Young teaches that biodegradable polymers should be used with the compositions recited therein (see abstract, p. 5, lines 27-31); one would therefore have recognized that the strategies of Wang could have been employed with a reasonable expectation of success in a composition comprising the cell types described by Young. Furthermore, Young teaches that a hydrogel may be used and Wang teaches an improved hydrogel for cell transplants; one would thus have been motivated to combine the teachings to arrive at the claimed invention and could have done so with a reasonable expectation of success. One of ordinary skill in the art would therefore have been motivated to combine the teachings of Young and Wang to arrive at the claimed invention. Further, although neither of the references teach compositions containing the specific concentration of cells recited in the claims, one of ordinary skill in the art would recognize that the concentration of cells could have been modified; thus, one would have recognized that the claimed concentration could have been arrived upon in the course of routine experimentation. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

9. Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (Biomaterials, October 2003, 24:3969-3980) in view of Young (WO 03/018040 A1; document cited in previous action) as applied to claims 1-3 and 5-7 above, and further in view of Calias et al. (US 6,749,865; document cited in previous action). Claims 1-3 and 5-7 are recited above. The claims further recite that said growth

factors are bFGF and EGF and that the growth factors are conjugated to polycarbophyll. The claims further recite that the biodegradable polymer gel is comprised of a water-soluble selected from the group consisting of: polymethylacrylate, poly-n-isopropylacrylamide, poly-2-hydrimethacrylate, polyvinyl alcohols, sodium alginate, and derivatives and copolymers thereof.

10. The teachings of Wang and Young are discussed in the rejections above. As discussed above, it would have been obvious to combine the references to arrive at nearly all elements of the claimed invention. Neither reference, however, teaches the use of growth factors that are conjugated to polycarbophyll.

11. Calius teaches biologically active conjugates comprising a biopolymer (such as polycarbophil or chitosan) and a therapeutic agent (such as a growth factor; abstract, col. 3, line 64-col. 4, line 19, col. 4, lines 49-67, col. 6, lines 54-67). The reference teaches that the conjugates are useful for drug delivery to specific cell and tissue types (col. 2, lines 12-20). One of ordinary skill in the art would have been motivated to use a conjugate for specific targeting to a cell type because the teachings of Young and Wang are directed to compositions comprising a cell-hydrogel matrix for tissue engineering. One would therefore recognize that the growth factors necessary to direct the growth of cells in these engineered matrices could be specifically targeted using the teachings of Calius. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings to arrive at the claimed invention because the cells of Young are known to be compatible with hydrogels, such as those taught by Wang, and with growth factors, such as those taught by Young and Calius. It would

therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

12. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (Biomaterials, October 2003, 24:3969-3980) in view of Young (WO 03/018040 A1; document cited in previous action) as applied to claims 1-3 and 5-7 above, and further in view of Edge (US 6,284,245). Claims 1-3 and 5-7 are recited above. The claims further recite that the attachment proteins are selected from the group consisting of laminin, fibronectin, and RGDS.

13. The teachings of Wang and Young are discussed in the rejections above. As discussed above, it would have been obvious to combine the references to arrive at nearly all elements of the claimed invention. Neither reference, however, teaches the use of laminin, fibronectin, and RGDS in the compositions.

14. Edge teaches compositions comprising neural retinal cells for the treatment of retinal disorders (abstract). The reference teaches that the compositions may comprise components that promote proliferation of the cells, such as laminin (col. 4, lines 40-52). One of ordinary skill in the art would have been motivated to add a component such as laminin to the compositions of the combined prior art because Edge teaches that the components are desirable because they promote proliferation of retinal cell types. One would therefore recognize that these components would be desirable in the compositions of Wang and Young and that they could have been added to the composition with a reasonable expectation of success. It would therefore have been

obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

15. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

16. Applicant's arguments, see p. 8, par. 2 of the response filed on June 22, 2010, with respect to the rejection(s) under 35 USC 103 in view of the Liu reference have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Wang reference cited above.

17. Regarding applicant's arguments that the references fail to teach the claimed invention because they are not directed to the preparation of a composition for the treatment of Parkinson's disease, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The treatment of Parkinson's disease is an intended use of the composition that is under examination. The compositions of the cited prior art would be suitable for use in a method for treating Parkinson's disease; thus, the prior art meets this limitation of the claims. Although applicant further argues that the cited prior art teaches away from a



method for the treatment of Parkinson's disease, it is noted that such a method is not recited in the claims. The claims are directed to a composition comprising cells and a polymer. Thus, applicant's argument has not been found to be persuasive. Although applicant further argues that the Young reference is not relevant to the claimed invention because the claimed invention is directed to a suspension of cells and the Young reference is directed to a graft, this is not found to be persuasive because the claims do not recite that the composition is a suspension. Thus, the features to which applicant refers are not recited in the instant claims.

18. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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